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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/848,727

Applicant(s)

GAU, VINCENT JEN-JR.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 21-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15 & 17 .                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election of Group I (Claims 1-20) in Paper No. 18 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 21-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 18.

### *Drawings*

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "920" ([0125], lines 2-3) and "905" ([0124], line 5) have both been used to designate silicon dioxide layer. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "909" has been used to designate both substrate and well. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: ref. #810 and #820 of figure 23. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Specification***

6. The abstract of the disclosure is objected to because it exceeded 150 words. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities:

It is unclear whether there are any missing parts from the large blank space between section [011] and section [012].

Appropriate correction is required.

8. Claims 1-20 are treated on the merit in this Office Action.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US Patent 5,200,051).

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor reacts with the analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43) (referring to claim 4). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34) (referring to claim 3). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claims 5 and 6). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 7-8 and 13). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 9). The biosensor comprise of three conductive electrodes (see fig. 2) (referring to claim 12). Figure 4 shows an electrode well structure (referring to claim 11). Therefore, the method of Cozzette et al. anticipates the presently claimed invention.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-2 and 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Heller et al. (US Patent 5,403,700).

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor reacts with the analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43) (referring to claim 4). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34) (referring to claim 3). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claims 5 and 6). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 7-8 and 13). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 9). The biosensor comprise

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of three conductive electrodes (see fig. 2) (referring to claim 12). Figure 4 shows an electrode well structure (referring to claim 11).

The method of Cozzette et al. does not expressly disclose that the adhesive metal layer is chromium.

Heller et al. disclose a biocompatible thin film electrical component (col. 1, lines 10-17). The film comprise of a silicon substrate (col. 1, lines 40-42), an adhesive layer that bond a metal layer to the substrate (col. 6, lines 54-68 to col. 7, lines 1-4). The adhesive layer is metal comprises of chromium or titanium.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a chromium metal adhesive as taught by Heller et al. in the method of Cozzette et al. One of ordinary skill in the art would have been motivated to include a chromium metal adhesive in the method of Cozzette et al. because Heller et al. have indicated that chromium and titanium are suitable metal adhesive and Cozzette et al. uses a titanium metal adhesive. Since applicant has not disclosed that a chromium metal adhesive solves any stated problem or is for any particular purpose, it appears that the invention would perform equally well with either chromium or titanium as metal adhesive.

13. Claims 1-2 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzette et al. (US Patent 5,200,051) in view of Han et al. (US Patent 6,268,161 B1).

Cozzette et al. disclose a method of electrochemical assay using a biosensor, which is an electrode, to detect changes in concentration of electroactive species (col. 46, lines 13-18). The method comprise of preparing a solution of an analyte/label of interest and contacting it with the

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biosensor (col. 46, lines 19-65). The receptor immobilized on the biosensor (referring to claim 20) reacts with the analyte forming a complex and the biosensor is in contact with the substrate, which reacts with label of the complex. This reaction initiates a sequence of steps, which effectuate changes in the concentration of the electroactive species, which are chemically measured (col. 46, lines 33-43). The measurement provides for the determination of the corresponding analyte concentration in the sample (referring to claim 1). The solution comprise of biological fluid (col. 18, lines 23-34). The substrate comprise of silicon, glass, or plastic (col. 25, lines 36-44) (referring to claim 15). The electrode comprise of gold or platinum (col. 25, lines 2-8) (referring to claims 16-17). A metal-substrate adhesive comprise of titanium (col. 25, lines 55-61) (referring to claims 2 and 18). The method further comprise of a calibration step (col. 64, lines 5-21). Figure 4 shows an electrode well structure (referring to claim 19).

The method of Cozzette et al. does not expressly disclose that calibration step comprising calibration solution and obtaining a signal.

Han et al. disclosed a biosensor for measuring the concentration of organic molecules in a solution (col. 1, lines 16-17). Han et al. claim a method of using the biosensor that included a calibration step (Han: col. 16, claim 20). The claim method step includes a control solution (calibration solution) and obtaining a signal.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include a calibration step comprising calibration solution and obtaining a signal as taught by Han et al. in the method of Cozzette et al. One of ordinary skill in the art would have been motivated to include a calibration step comprising calibration solution and obtaining a signal in the method of Cozzette et al. for the advantage of determining the



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performance of the electrode before the analysis of the sample. Since both Cozzette et al. and Han et al. disclose a method of measuring the concentration of the organic molecules in a solution (Cozzette: col. 46, lines 13-18; Han: col. 1, lines 16-17).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct  
January 27, 2003

  
**PADMASHRI PONNALURI**  
**PRIMARY EXAMINER**